

make comparison of results between different studies difficult and standardization is called for. The quantitative imaging biomarker alliance (QIBA) is an example of an initiative that aims to *improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, patients and time.*

Whereas standardization in methodology is important for quantification, it has to be able to accommodate emerging new techniques. It is untenable to continue using outdated methods, simply because earlier studies did not have access to more advanced equipment. Therefore, within a multicenter project using quantitative MRI for imaging cancer in the prostate and cervix, we developed a procedure that allows each center to use the optimal sequences for their scanner. In a series of phantom and volunteer experiments these sequences are benchmarked against well-established sequences which are robust, but typically too slow for clinical use. Consistent quantification with a bias of a few percent between different scanners and institutes was feasible for T2 mapping, as well as for diffusion-weighted MRI. With newer scanners and sequences typically more precise results were obtained. This strategy is therefore a way to achieve consistency between quantitative results from different centers and studies.

SP-0292

The issue of the quality of data in clinical trials

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Clinical trials are considered as the most rigorous way to prospectively evaluate the efficacy and toxicity of treatments. When randomized designs are used they also provide comparative effectiveness between several therapies. Good Clinical Practice is the universal ethical and scientific quality standard for conducting clinical trials and applies to all aspects of the clinical trial process. Quality is viewed as a continuum, going from trial design to analysis and reporting. The quality of a clinical trial at an investigator site is usually assessed by sponsor audits and regulatory inspections, but radiation oncology trials can, through RTQA procedures, include an innovative means of quality assessment which can ultimately generate data and hypotheses. The Clinical Trials Transformation Initiative has defined quality as “the ability to effectively answer the intended question about the benefits and risks of a medical product (therapeutic or diagnostic) or procedure, while assuring protection of human subjects”.

The different issues of quality in clinical trials will be discussed, including trial design, statistical hypotheses, interventions, data recording and monitoring, statistical analysis, trial reporting and interpretation. Means to improve trials quality and generalization of trials' results will also be discussed. All the limitations to data quality in prospective trials described will also apply to other forms of clinical research, such as data-mining, and are usually minimized and controlled in randomized trials. It is crucial to allow external audit and meta-analyses, as these procedures can identify and potentially reduce biases. Ultimately the reader is the last judge of trial quality through the critical reading of medical literature.

Symposium: Risk management: QA and safety 1

SP-0293

The ESTRO task force on risk management - A Status Report

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Aim: ESTRO has formed a task force on risk management within radiation oncology (RO). ESTRO represents all the professionals working within RO and is therefore the most appropriate partner to work with on issues relating to risk and risk management within radiotherapy. One example is in the implementation of the latest EU directive on basic safety standard in radiation protection, which will make reporting and learning from incidents and near incidents a legal requirement. ESTRO works closely with the National Societies in EU and is ideally positioned to inform and advise on this and all other related issues.

Methods: The remit of the working group was to define the specific tasks that should be carried out. These include:

- To develop a body of knowledge in order to position ESTRO such that they can inform and influence policy with respect to risk management in radiotherapy at the level, for instance of the European Commission
- To prepare and disseminate information to the National Societies and the ESTRO community on important developments in the area of risk management and incident reporting and learning that they should be aware of.
- To position ESTRO as an interface with other professional bodies such as ASTRO/AAPM to ensure consistency of approach internationally.
- To liaise between European and global bodies, the National Societies and the ESTRO community to advise with respect to effective implementation of the new EURATOM Directive.
- To carry out a scoping exercise of all the current activities in the area of risk management and incident learning specifically to identify variations and inconsistencies.

- Incident Learning Systems (ILS):
 - • ROSIS, SAFRON (IAEA)
 - • RO-ILS (ASTRO/AAPM)
 - • National Reporting and Learning System - NRLS with specific coding for RT (UK)
 - • Canadian Partnership for Quality in Radiotherapy - CPQR (Ca)
 - • Etc...

Consistent with the requirements of the new EURATOM Basic Safety Standards which will mandate new measures in relation to risk management in radiotherapy, the ESTRO, as the European professional body in radiotherapy should be in a position to give direction in relation to (for example):

What should be considered a mandatory reportable event
Carrying out prospective analysis when new technology is introduced

Implementing a registration and analysis of events relating to actual or potential unintended exposure

- To prepare and deliver guidelines and education programmes to enable compliance with national legislation in the area
- To monitor European and international activities on an ongoing basis and update the ESTRO as appropriate
- To prepare and disseminate information to the public on how safety is already a key focus in radiotherapy generally and the on-going efforts to ensure safety issues remain central to radiotherapy practice.

Conclusion: The aim of the task force is to position ESTRO at the forefront of Safety and Risk Management in radiation therapy by

- Collaboration with professional societies within first of all in EU/Europe but also with other organisation within RO
- Preparation of guidelines and educational material
 - Information and dissemination of present and future EURATOM directives.

SP-0294

AAPM safety profile assessment results from the first year of use

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Purpose: Quality and safety improvement is a multidimensional problem. Many recommendations for best practices have been put forth in the last five years. A recent review of seven authoritative documents revealed no fewer than 117 separate recommendations. These recommendations span the spectrum from quality control to prospective risk assessment to incident learning and safety culture. With such a wealth of information, it is challenging to absorb and implement quality improvement recommendations in a busy clinical environment. To address this issue, the American Association of Physicists in Medicine (AAPM) has developed the Safety Profile Assessment (SPA), a freely-available online tool designed to probe key aspects of quality and safety. This report describes the development of the SPA and its first year of use.

Methods: The SPA was developed over a two year period by a multi-disciplinary panel of experts using a consensus process. The resulting tool consists of 92 indicator questions designed to gauge the most important dimensions of quality and safety. The SPA was pilot tested in 21 volunteer clinics and released for general use in July 2013. Anonymous survey data were collected to gauge users' experience. The SPA was also analyzed with respect to the widely-accepted dimensions of quality from Donabedian.

Results: In the first year of use, 107 users completed the SPA. The online tool provides a (graphical) benchmarking of answers against all other respondents in the database and the ability to track responses over time. An annotated bibliography is available for each indicator question, and the user can download a safety and quality tracking spreadsheet to guide in the implementation of improvements. Classifying the indicator questions according to Donabedian's quality categories yielded the following results: process issues (62%), structural issues (27%) and outcomes (8%). In pilot testing the SPA required an average of 1.3 hours to complete. The majority of respondents (59%) had assembled a multidisciplinary group to complete the SPA of 3.9 members on average. With a 69% response rate to the survey, respondents indicated that SPA was easy or very easy to use

(70%) and that they would definitely or very probably complete the SPA again (63%).

Conclusions: The Safety Profile Assessment is a freely available online tool intended to provide a practical means for assessing the quality and safety environment in a radiation oncology clinic. The tool has been reviewed favorably by the first cohort of users.

SP-0295

MARR project for risk assessment results of the pilot test

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Purpose: The goal of the MARR project is to find a means to implement a risk analysis methodology among radiotherapy professionals.

This project is coordinated by the Spanish Professional Societies of Radiotherapy Oncology (SEOR), Medical Physics (SEFM), Radiation Protection (SEPR) and Radiotherapy Technologists (AETR).

Materials and Methods: The risk methodology chosen was the simplified dedicated Radiotherapy Risk Matrix and its associated software tool SEVRRRA, developed by Foro Iberoamericano de Organismos Reguladores (FORO). This method has been proved in 44 radiotherapy services of 7 different countries.

The risk matrix is an easy to use semi quantitative method that consists in analyzing all initiating events that can lead to an error in the treatment if the measures put in place to avoid it (barriers) fail. As a first stage in the MARR project, the initiating events and barriers were adapted to the current radiotherapy practice in Spain.

The risk is defined as a combination of three parameters: the frequency of occurrence of the event, the severity of the potential consequences and the probability of failure of the set of existent barriers. The risk matrix provides the resulting risk level from this combination.

The methodology allows a second deeper analysis on those errors resulting in a higher associated risk

The MARR project was carried out in 10 Spanish Hospitals during the period 2013 -2014 and involved:

- The training of the participating professionals (a working team composed by a radiotherapy oncologist -RO-, medical physicist -MP- and radiation therapy technologist -RTT- from each hospital) in the use of the risk matrix methodology and SEVRRRA

- The completion of the risk analysis in every hospital

- The development of a risk analysis guide based on the results and the feedback provided, to facilitate the implementation of this method in other hospitals.

Results: The project is finished. In the following table a list of the initiating events, barriers and reducers where some modifications were introduced as a consequence of the feedback from participating hospitals is shown:

	Initial	Modified	Added
Initiating events	124	61	14
Barriers	104	30	29
Frequency reducers	47	10	19
Consequence reducers	32	10	9

The main advantages of the methodology declared by the participants are: